

## REMARKS

Applicants submit this Amendment in response to the Office Action mailed on March 8, 2007.

The specification has been amended as followed. The paragraph starting on page 4, line 24, has been amended as suggested by the Examiner to more accurately describe Figure 1. The specification has been amended in numerous places to correctly indicate the use of trademarks. The paragraph starting on page 16, line 7, has been amended to provide the correct current address of the American Type Culture Collection (ATCC).

The claims have been amended as follows. Claims 1 and 2 have been amended to call for the amino acid sequence of SEQ ID NO: 4. Claims 3-5 and 11-14 have been canceled in view of the amendments to claims 1 and 2. Claims 6-10, 18-35, and 40-45 have been canceled as being drawn to a non-elected invention. Claims 15, 17, 36, and 37, which are withdrawn, have been amended as follows. Claim 15 has been amended to call for a nucleic acid that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:4. Claim 17 has been amended to call for the hybridization that was previously called for in claim 15. Claim 36 has been amended to depend from claim 1. Claim 37, which depends from claim 36, has been amended to specify that the antibody selectively binds to the polypeptide of SEQ ID NO:4. New claims 46 and 47 have been added. Support for these new claims is found in the specification in Example 13, on pages 32-34.

## OBJECTIONS TO THE SPECIFICATION

I. The specification has been amended, as suggested by the Examiner, to more accurately describe Figure 1.

II. Trademark recitations throughout the specification have been amended to be capitalized.

III. The address of the American Type Culture Collection has been corrected to reflect the new address in Manassas, VA.

## REJECTIONS OF THE CLAIMS

I. Scope of Enablement under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 1-5 and 11-14 under 35 U.S.C. §112, first paragraph, as not being enabled to the full scope claimed. Applicants traverse the rejection of these claims on this ground.

Applicants respectfully submit that it is well within the capabilities of one skilled in the art, without undue experimentation, to determine isolated polypeptides that are 50%, 60%, 70%, 80%, or 90% homologous with SEQ ID NO: 4, wherein antibodies that bind to the polypeptide inhibit the adherence or internalization of *Streptococcus uberis* to bovine mammary cells. Applicants further respectfully submit that it is well within the capabilities of one skilled in the art, without undue experimentation, to determine isolated polypeptides comprising at least 6, 7-10, 9-12, or 10-15 sequential amino acids of SEQ ID NO: 4, wherein antibodies that bind to the polypeptide inhibit the adherence or internalization of *Streptococcus uberis* to bovine mammary cells.

The Examiner has provided reasoning that shows that such experimentation may be long and arduous. However, it is submitted that such experimentation is not beyond that which is routinely performed by those of skill in the relevant art.

However, in order to expedite prosecution on the portion of the claims that the Examiner has found to be enabled, Applicants have amended claim 1 to omit the portion of the claim stated by the Examiner to be non-enabled and have canceled claims 3-5 and 11-14 in view of the amendment to claim 1. Claim 2 has been amended to call for the polypeptide of claim 1 that consists of the amino acid sequence of SEQ ID NO: 4.

Applicants submit that the amendment to claims 1 and 2, and the cancellation of claims 3-5 and 11-14, overcomes the rejection of these claims as not being enabled to the full scope claimed. Accordingly, the Examiner is respectfully requested to withdraw this basis of rejection as to claims 1 and 2.

## II. Indefiniteness under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1-5 and 11-14 under 35 U.S.C. §112, second paragraph, as being indefinite because of the recited limitation: “wherein an antibody that binds to the polypeptide . . . cells.” Applicants traverse the rejection of these claims on this ground.

Applicants submit that the claim, as initially filed, is clear to one skill in the art. It is further submitted that the rejection of these claims on this ground is moot because claim 1 has been amended to remove this limitation and claim 11 has been canceled.

III. Anticipation under 35 U.S.C. §102(b)

A. Drmanac, WO 01/75067

The Examiner has rejected claims 1 and 11 under 35 U.S.C. §102(b) as being anticipated by Drmanac, WO 01/75067. As stated by the Examiner, Drmanac discloses an isolated polypeptide comprising an amino acid sequence that has 57.5% sequence homology to the amino acid sequence of SEQ ID NO: 4 and that has 6 sequential amino acids of SEQ ID NO: 4.

Applicants submit that the rejection of these claims on this ground is moot because claim 1 has been amended to remove the limitation pertaining to the percent homology to SEQ ID NO: 4 and claim 11 has been canceled.

B. Alexandrov, EP 1033405

The Examiner has rejected claims 11 and 12 under 35 U.S.C. §102(b) as being anticipated by Alexandrov, EP 1033405. As stated by the Examiner, Alexandrov discloses an isolated polypeptide comprising 7 sequential amino acids of SEQ ID NO: 4.

Applicants submit that the rejection of these claims on this ground is moot because claims 11 and 12 have been canceled.

C. Parks, in Proceedings of the 40th Annual Meeting of National Mastitis Council, National Council Incorporated, pages 247-248, February 2001

The Examiner has rejected claims 1-5 and 11-14 under 35 U.S.C. §102(b) as being anticipated by the disclosure of Parks, in Proceedings of the 40th Annual Meeting of

National Mastitis Council, National Council Incorporated, pages 247-248, February 2001.

Applicants traverse the rejection of these claims on this ground.

The Manual of Patent Examination Procedures (MPEP) §2121.01 clearly states that, in order to reject a claim as being anticipated in view of the disclosure of a prior art reference, the reference must contain an enabling disclosure of the claimed invention. This section of the MPEP states as follows:

2121.01 Use of Prior Art in Rejections Where Operability Is in Question

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. <Mayo Found. For Med. Educ. & Research>*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). (emphasis by underlining added)

Applicants submit herewith a Declaration of Stephen P. Oliver, one of the named inventors of the present application and a co-author of the cited Parks reference. In his Declaration, Dr. Oliver establishes that the Parks reference is not an enabling disclosure. This is because the claimed isolated polypeptide of the present invention is not produced by the process disclosed in Parks. Rather, the process of Parks results in an extraction of a large number of

polypeptides from the surface of *Streptococcus uberis* and discloses that the presence of a lactoferrin-binding protein is detected within, but not isolated from, a mixture of the extracted polypeptides. However, much additional experimental work must be performed in order for one of skill in the art to be able to obtain the isolated polypeptide. Such additional experimental work was performed by the present inventors and culminated in the process disclosed in Example 6 of the present application.

In view of the Declaration of Stephen P. Oliver, Applicants submit that the rejection of the claims as being anticipated by the disclosure of Parks is overcome and the Examiner is respectfully requested to withdraw the rejection of the claims on this ground.

#### IV. Objections to the claims

The Examiner has objected to the claims for the incorrect recitation "Seq. ID No." as opposed to the correct recitation "SEQ ID NO:." The claims have been amended accordingly to correctly recite this term.

#### V. Previous Restriction Requirement

In the Office Action mailed on September 28, 2006, the Examiner required a restriction of the invention between 8 inventions. Applicants elected, with traverse, to presently prosecute claims of invention I, claims 1-5 and 11-14. The claims of inventions II, IV, V, VII, and VIII have been canceled. The claims of inventions III and VI have been withdrawn but have not been canceled. In the present Amendment, the claims of inventions III and VI have been amended to either call for all of the limitations of claim 1 or to depend from claim 1. In view of

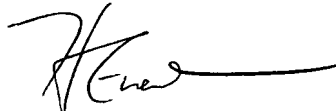
these amendments, the Examiner is respectfully requested to rejoin the claims of inventions III and VI in accordance with the provisions of MPEP §821.04.

Additionally, the new claims submitted with the present Amendment, claims 46 and 47, either call for all of the features of claim 1 or depend from claim 1. Accordingly, the Examiner is respectfully requested to examine these new claims at this time.

#### CONCLUSION

Applicants submit that the claims, as amended herein, including the claims previously withdrawn but not canceled and claims newly added herein, are in condition for allowance and request an early notice to that effect.

Respectfully submitted,



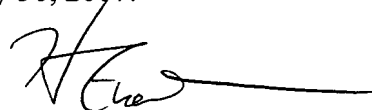
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#### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 30, 2007.

Dated: \_\_\_\_\_

5/30/07



Howard M. Eisenberg